Message

From: Gibbons, Catherine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2AC775A35A0945718EDC7E02F50E6C12-GIBBONS, CATHERINE]
Sent: 2/9/2016 5:45:11 PM
To: Newhouse, Kathleen [Newhouse.Kathleen@epa.gov]
Subject: RE: News Update: Advisors May Temper Critical BaP Review To Advance IRIS Assessment (Inside EPA)

That really is a victory! Ughhh this is always the way it USED to be. What if, for all new assessments, we pledged to do updates every 5 years to cover all these people freaking out about new studies that are needed? Do you think that would work without a court mandate?

From: Newhouse, Kathleen
Sent: Tuesday, February 09, 2016 11:34 AM
To: Gibbons, Catherine <Gibbons.Catherine@epa.gov>
Subject: RE: News Update: Advisors May Temper Critical BaP Review To Advance IRIS Assessment (Inside EPA)

Overall, this is good press. We were able to shift focus somewhat to suggestions they made that were very high LOE with little payoff. I'm glad this was reported in the press and hopefully some of the final report language will be tempered to consider that a final BaP tox review is needed in a timely manner.

From: Gibbons, Catherine
Sent: Tuesday, February 09, 2016 7:51 AM
To: Newhouse, Kathleen <Newhouse.Kathleen@epa.gov>
Subject: FW: News Update: Advisors May Temper Critical BaP Review To Advance IRIS Assessment (Inside EPA)

...congratulations? They always try to make even good outcomes sound like EPA is terrible.

From: Shams, Dahnish
Sent: Tuesday, February 09, 2016 9:13 AM
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Subject: News Update: Advisors May Temper Critical BaP Review To Advance IRIS Assessment (Inside EPA)

RISK POLICY REPORT - 02/09/2016

Advisors May Temper Critical BaP Review To Advance IRIS Assessment

February 08, 2016

Despite raising concerns about draft recommendations in a review of EPA's draft benzo(a)pyrene (BaP) assessment, the agency's chartered Science Advisory Board (SAB) has approved the draft peer review of the assessment of the chemical's human health risks pending minor changes.

Members of the chartered SAB suggested that some of the recommendations developed by its Chemical Assessment Advisory Committee may add a lot of work for EPA and delay the Integrated Risk Information System (IRIS) assessment without being worthwhile. But after several hours of discussion Jan. 26, the executive panel voted unanimously to approve the draft peer review pending minor changes undertaken by the subpanel's chair and approved by the chartered SAB chairman before the report is transmitted to the agency.

The draft peer review raises concerns about several of the risk estimates that EPA calculated, including its skin cancer risk estimate, the first that the IRIS program has produced. That number has been scrutinized by stakeholders who have argued that the number is overly conservative (*Risk Policy Report*, Sept. 8). It is not entirely clear how the final report will be altered, but some advisors' concerns about the amount of work that some of the recommendations represent for EPA may temper criticism in the draft report.

In its draft report, dated Dec. 21, the peer review panel writes that it "commends the agency's efforts in deriving the IRIS Program's first dermal slope factor (DSF). However, the proposed DSF is not sufficiently supported scientifically."

The draft report goes on to suggest that EPA add two additional toxicology studies to strengthen its DSF analysis and also "more thoroughly review the evidence of skin cancer in studies of coke, steel and iron, coal gasification and aluminum workers given their relevance for evaluating the appropriateness of using the mouse-based risk assessment model for predicting skin cancer risk in humans." *Relevant documents are available on InsideEPA.com. (Doc. ID: 188659)*

One of the executive committee members, Susan Felter, a research fellow with Procter & Gamble, questioned whether the report provided a good recommendation for EPA to improve its DSF. "I'm wondering if there was discussion around other methods, other methodology," she said. "I'm a little concerned the message is, 'We're concerned, but you need to justify it better.' . . . What additional justification can be given? That's my concern. This is setting a precedent."

Another SAB member, Michael Dourson of the nonprofit consulting group Toxicology Excellence for Risk Assessment, suggested moving the dermal slope factor out of the main report and instead adding it as an appendix, though there was no further discussion of the suggestion.

Elaine Faustman, a toxicology professor at the University of Washington and the chairman of the BaP peer review panel, said that EPA managers have suggested that they will host a workshop on the BaP DSF, and asked EPA speakers to provide some clarification.

"We are planning to do some more work and discussing with the public on this," IRIS Director Vincent Cogliano told the science advisors. "The idea of coming up with a general [DSF] approach [may be] difficult because many chemicals have different properties. But there is an agency need for a BaP [DSF]. This is pretty much the only chemical that we hear that from our program and regional offices."

Cogliano added, "We'd like to do this for BaP and then perhaps" later decide how to craft more general guidance on crafting DSFs.

Despite the critical review, Cogliano and some of the executive committee members questioned whether the detailed peer review suggested more work than was practical or reasonable for EPA to undertake in order to finish the BaP assessment.

"You have to consider payoff," Cogliano said of some of the draft report's recommendations. He pointed to one recommendation requiring additional analysis which he described as "a lot of work," before adding that the International Agency for Research on Cancer (IARC) performed that analysis about five years ago. "I think that's a lot of work to replicate what IARC has already done. I'm not sure the level of effort in constructing these tables is worth it."

Cogliano also asked the committee to reconsider a draft recommendation regarding studies that the committee thought were missing from EPA's assessment and should be included. He noted that IRIS staff started the assessment before 2013, when software was adopted to assist with literature searches. He called the recommendation "A large effort, and to what benefit? I'd like to take those recommendations to say, 'Move in this direction, but not hold up this assessment [for that.]'"

Cogliano's concerns were echoed by one of the chartered SAB committee members, Gina Solomon, deputy secretary for science and health with California EPA. "I think it's the most thorough report I've ever reviewed. Extremely detailed, very well organized and very clear," Solomon said. "My only concern being in the greater scope of the IRIS assessment. If the goal is to help the program move forward more quickly, the reviewers are demanding a lot of detailed work from EPA."

Solomon added that she shared some of Cogliano's concerns. "As reviewers we do have to think about what is really important, critical to the document and making sure that EPA is identifying the appropriate hazards . . . and coming up with well supported risk numbers. But we also have to be careful not . . . to get too carried away and trying to make each of these documents perfect."

The draft review agrees with "EPA's conclusions that developmental neurotoxicity, developmental toxicity, male and female reproductive effects, and immunotoxicity are human hazards of BaP exposure. In addition, the SAB agrees with the classification of BaP as carcinogenic to humans by all routes of exposure . . . Furthermore, the SAB agrees that BaP-induced tumors arise primarily through a mutagenic mode of action resulting from BaP-induced DNA damage."

But the report questions EPA's conclusions that cardiovascular and nervous system toxicity are not potential human risks, saying that "the evidence presented in the assessment does not support EPA's conclusion . . ."

The draft report goes on to question various aspects some of EPA's other quantitative risk estimates, particularly the noncancer calculations. Regarding the oral reference dose (RfD), the amount that EPA estimates can be ingested daily over a lifetime without experiencing adverse health effects, the report agrees with EPA's choice of neurodevelopmental effects as the correct basis for the calculation, but suggests the agency needs to "provide a firmer justification for not selecting" reproductive outcomes as critical endpoints.

For the reference concentration (RfC), analogous to the RfD but for inhalation risk, the draft report concludes that "the RfC value provided in the assessment is not scientifically supported." It explains that while the reviewers agree with the study selected for the calculation, EPA used only this study, which has some "technical deficiencies," and recommends that EPA consider two additional studies to add to the RfC risk estimate.

Similarly, the report agrees with the studies and models used to calculate the oral cancer risk estimate, but recommends that EPA provide better justification "for the derivation of the final slope factor solely based on a single-sex mouse study that produced the largest cancer slope factor. The SAB suggests that data from all studies be incorporated in the derivation of the oral cancer slope factor."

The report largely agrees with the basis for the inhalation cancer risk estimates, but urges EPA to better explain key assumptions. --
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